

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ALLERGAN USA, INC., ALLERGAN  
HOLDINGS UNLIMITED COMPANY and  
EDEN BIODESIGN, LLC,

Plaintiffs,

v.

C.A. No. 19-1727-RGA

MSN LABORATORIES PRIVATE  
LIMITED and MSN PHARMACEUTICALS  
INC.,

Defendants.

**MEMORANDUM OPINION**

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Wilmington, DE; Lisa B. Pensabene, Hassen A. Sayeed, Daniel O'Boyle, Carolyn Wall, James  
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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Defendant's motion for leave to amend. (D.I. 374). The motion has been fully briefed. (D.I. 374, 388, 395). For the reasons set forth below, Defendant's motion is denied.

## **I. BACKGROUND**

On September 13, 2019, Plaintiffs Allergan USA, Inc., Allergan Holdings Unlimited Company, and Eden Biodesign, LLC (collectively, "Allergan" or "Plaintiffs") filed their Complaint alleging infringement of U.S. Patent Nos. 9,675,587 (the "'587 Patent") and 10,188,632 (the "'632 Patent") against MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. ("MSN" or "Defendant"). The infringement is based on MSN filing Abbreviated New Drug Application ("ANDA") No. 213576 with the FDA.

Over the course of litigation, Allergan filed continuation applications and prosecuted patents belonging to the patent family at issue. Allergan later obtained U.S. Patent Nos. 11,007,179 (the "'179 Patent"), 11,090,291 (the "'291 Patent"), and 11,160,792 (the "'792 Patent"), and asserted them against MSN in July 2021, August 2021, and November 2021, respectively. The actions asserting these patents were consolidated with this action.

Allergan obtained U.S. Patent Nos. 11,229,627 (the "'627 Patent") and 11,311,516 (the "'516 Patent") in January 2022 and April 2022, respectively. By agreement of the parties (D.I. 339), Allergan filed an Amended Complaint on April 28, 2022, asserting the '627 Patent and the '516 Patent against MSN. MSN filed its Answer on May 16, 2022. (D.I. 346). MSN filed the instant motion on July 22, 2022.

## **II. LEGAL STANDARD**

Federal Rule of Civil Procedure 15(a)(2) states that, apart from amendments as a matter of course, "a party may amend its pleading only with the opposing party's written consent or the

court's leave. The court should freely give leave when justice so requires." FED. R. CIV. P. 15(a)(2). The Third Circuit has instructed that "absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless 'denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.'" *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 1173, 1196 (3d Cir. 1994)) (emphasis omitted). An amendment is futile if it "would fail to state a claim upon which relief could be granted." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The futility analysis follows the standard that applies to a motion under Rule 12(b)(6). *Id.*

A request to amend filed after the court's deadline to amend must also meet the "good cause" standard of Rule 16(b)(4). *Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020). Rule 16(b)(4) provides, "A schedule may be modified only for good cause and with the judge's consent." FED. R. CIV. P. 16(b)(4). "'Good cause' exists when the [s]chedule cannot reasonably be met despite the diligence of the party seeking the extension." *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009). Unlike Rule 15(a), the Rule 16(b) standard focuses on the "diligence of the movant, and not on prejudice to the non-moving party." *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at \*4 (D. Del. May 21, 2009). "A party must meet [Rule 16(b)'s] standard before a district court considers whether the party also meets Rule 15(a)'s more liberal standard." *Premier Comp*, 970 F.3d at 319.

### III. DISCUSSION

On April 28, 2022, Allergan filed its Amended Complaint (D.I. 341) adding the infringement claims against MSN pertaining to the '627 Patent and the '516 Patent. MSN filed its Answer on May 16, 2022.

The timeline following MSN's filing is in dispute. According to MSN, it "diligently raised the issue of unclean hands with [Allergan] on May 26, 2022 and met and conferred to reach a compromise." (D.I. 374 at 5). MSN does not provide any exhibit (*e.g.*, an email thread) to support its allegation of communicating this issue to Allergan on May 26, 2022. Allergan states that, to the contrary, it was Allergan that raised the issue on June 24, 2022. (D.I. 388 at 8). The only documentation in the record supports Allergan's position. (*See* D.I. 388-1, Exs. A&B). In its reply, MSN appears to concede the point. (*See* D.I. 395 at 3 (arguing "informal notice based on Sun's complaint"))).

On May 27, 2022, MSN and Sun (another defendant in the consolidated case) served their final invalidity and unenforceability contentions relating to the '627 and '516 patents. (*See* D.I. 350).<sup>1</sup> Allergan states that these contentions were the first time MSN asserted an unclean hands defense for the '627 Patent and '516 Patent. (D.I. 388 at 4). Allergan further states that it was only after Allergan read MSN's and Sun's joint opening invalidity report, served on June 17, 2022, that Allergan reached out to MSN to clarify if MSN was asserting a defense of unclean hands. (*Id.*). Allergan and MSN met and conferred on June 27, 2022. (D.I. 374-3, Ex. C; D.I. 388-1, Ex. B).

On July 22, 2022, MSN sought to amend its May 16, 2022 Answer to add counterclaims and affirmative defenses alleging that the '516 Patent, the '627 Patent, and the '291 Patent are unenforceable under the doctrine of unclean hands.

#### **A. RULE 16(b)(4) DILIGENCE**

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<sup>1</sup> Defendant Sun also filed an Amended Answer (D.I. 349) alleging similar claims and affirmative defenses based on the doctrine of unclean hands, which MSN explicitly refers to in its briefing. (D.I. 374 at 3).

MSN asserts that good cause exists for allowing leave to amend. MSN claims it was diligent in raising the issue of unclean hands with Allergan on May 26, 2022. (D.I. 374 at 5; D.I. 395 at 3). The record does not support the date of this claimed diligence.

Allergan counters that MSN cannot show good cause because MSN was not diligent. Allergan argues that MSN was not diligent because Allergan needed to prompt MSN before MSN acted to amend the pleadings to add the proposed affirmative defense and counterclaims. (D.I. 388 at 8). Allergan also argues that MSN was not diligent because MSN was in possession of the information to form its claims of unclean hands in February 2022, five months prior to filing this motion. (*Id.* at 7-8).

I find that MSN is unable to show good cause because it was not diligent. Even if I were to credit MSN with “informal notice” some time before June 24<sup>th</sup>, MSN was not diligent. MSN alleges that it gathered the facts necessary to raise the proposed amendment “[i]n the course of reviewing the pop-up patents asserted against” MSN. (D.I. 374 at 4). The only sources of evidence that MSN cites to in its motion are the patents at issue (i.e., the ’291 Patent, the ’587 Patent, the ’632 Patent, ’627 Patent, and ’516 Patent), the prosecution histories of patent applications in the patent family (U.S. Patent Application Nos. 13/829,984, 15/588,304, 16/213,083, and 16/459,947), and deposition testimony taken on February 16, 2022 from Dr. Costello, one of the named inventors on the patents. (D.I. 374-1, Ex. A). These are all sources of information that MSN possessed before it filed its Answer on May 16, 2022. MSN has not cited to any facts or sources of information that it needed to bring its claims for unclean hands but which it lacked on May 16, 2022.

The date the answer was due—May 16, 2022—was set by court order. (D.I. 340). MSN concedes that the “facts were in existence before the scheduling deadline,” but cites to *Galderma*



*Labs. Inc. v. Amneal Pharm.*, 2013 WL 5461611 (D. Del. Sept. 30, 2013) for the proposition that good cause can be found provided the movant “was diligent after the facts came to its attention.” (D.I. 374 at 5-6). The facts in *Galderma* are distinguishable from the facts here. In *Galderma*, the movant only learned of the facts through deposition testimony that occurred months after the deadline to amend pleadings. *Id.* at \*1. To put it another way, the court found good cause in *Galderma* because the movant first possessed the information after the deadline to amend the pleadings. In the present case, MSN possessed all the relevant information to bring its counterclaims and defenses of unclean hands at the time Allergan filed its amended complaint.

Furthermore, the movant in *Galderma* brought its motion to amend within one month of learning of the new facts. *Id.* In the present case, MSN is bringing its motion almost five months after it obtained the inventor’s testimony and two months after its Answer was due. The Rule 16(b)(4) standard does not allow “an inability to timely amend a pleading within the scheduling order deadline [to] excuse[] a party from exercising diligence in seeking leave to amend outside of the deadline.” *NRT Tech. Corp. v. Everi Holdings Inc.*, 2022 WL 354291, at \*3 (D. Del. Jan. 11, 2022). MSN’s bare claims of diligence in reviewing the patents are insufficient. This court has found excuses of dealing with a “tortuous” record and common litigation activities do not excuse delay. *See Pfizer Inc. v. Sandoz Inc.*, 2013 WL 5934635, at \*4 (D. Del. Nov. 4, 2013). MSN’s claim that it was diligent is further undercut by Allergan’s exhibits showing that it was Allergan who was proactively seeking clarification as to whether MSN was intending to pursue claims of unclean hands, rather than MSN taking the initiative. (D.I. 388-1, Ex. A.).

I find that MSN cannot show good cause under Rule 16(b)(4) because it was not diligent. It appears that MSN was in possession of all the relevant facts to assert its claims and defenses of unclean hands at the time it filed its Answer. MSN has failed to point to new information it came

to possess after the May 16 deadline, or any other explanation for why it was unable to timely plead unclean hands. Therefore, MSN has not shown good cause under Rule 16(b)(4).

Because I find that MSN has not satisfied Rule 16(b)(4)'s standard, it is not necessary to determine whether MSN meets Rule 15(a)'s requirements. *See Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020).

#### **IV. CONCLUSION**

For the reasons stated above, Defendant's motion is DENIED.

An appropriate order will issue.